

# DIRECTIVES

## COMMISSION DIRECTIVE 2011/3/EU

of 17 January 2011

### amending Directive 2008/128/EC laying down specific purity criteria on colours for use in foodstuffs

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

authorised comply with safe conditions of use, Directive 2008/128/EC should therefore be amended.

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives<sup>(1)</sup>, and in particular Article 30(5) thereof,

After consulting the European Food Safety Authority (EFSA),

Whereas:

- (1) Commission Directive 2008/128/EC<sup>(2)</sup> sets out the specific purity criteria concerning colours for use in foodstuffs, which colours are mentioned in European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs<sup>(3)</sup>.
- (2) Under Article 30(4) of Regulation (EC) No 1333/2008 specifications of the food additives covered under paragraphs 1 to 3 of that Article (which include also additives authorised under Directive 94/36/EC) shall be adopted, in accordance with Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings<sup>(4)</sup>, at the moment those food additives are entered in the Annexes in accordance with those paragraphs.
- (3) Since the lists have not yet been drawn up, and in order to ensure that the modification of the Annexes to Directive 94/36/EC pursuant to Article 31 of Regulation (EC) No 1333/2008 is effective and that additives so

- (4) The European Food Safety Authority (hereinafter 'the Authority') has assessed the information on the safety in use of lycopene as a food colour from all sources in its opinion of 30 January 2008<sup>(5)</sup>. The sources that were considered were the following: (a) E160d Lycopene obtained by solvent extraction of the natural strains of red tomatoes (*Lycopersicon esculentum* L.) with subsequent removal of the solvent, (b) synthetic lycopene and (c) lycopene from *Blakeslea trispora*.
- (5) Current legislation lays down specifications only for lycopene of red tomatoes and needs to be modified respectively by including the other two sources. Specifications of lycopene extracted from red tomatoes need also to be updated. Dichloromethane does not need to be listed in the list of the extraction solvents, as it is not used any more for lycopene of red tomatoes, according to the information received from stakeholders. Maximum limit for lead needs to be lowered due to safety reasons, and the reference on heavy metals is too generic and not relevant any more. In addition the reference on natural strains needs to be updated according to Regulation (EC) No 1829/2003 of the European Parliament and of the Council<sup>(6)</sup>.
- (6) Dichloromethane (methylene chloride) is being reported to be used for manufacturing ready-to-sale formulations of lycopene, mentioned also in the Authority's opinion

<sup>(1)</sup> OJ L 354, 13.12.2008, p. 16.

<sup>(2)</sup> OJ L 6, 10.1.2009, p. 20.

<sup>(3)</sup> OJ L 237, 10.9.1994, p. 13.

<sup>(4)</sup> OJ L 354, 31.12.2008, p. 1.

<sup>(5)</sup> Scientific opinion of the panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the European Commission to provide a scientific opinion on the safety of use of 1. lycopene obtained from a fermentation process with *Blakeslea trispora* as a food colour in the food categories and use levels as proposed by the applicant and 2. synthetic lycopene as a food colour in the food categories listed in Annex III and Annex V, part 2 to Directive 94/36/EC on food colours for use in foodstuffs, 3. taking into account the various requests concerning lycopene currently under consideration including the re-evaluation of lycopene from tomatoes as part of the systematic re-evaluation of all food colours. The EFSA Journal (2008) 674, 1-66.

<sup>(6)</sup> OJ L 268, 18.10.2003, p. 1.

on Safety of 'Lycopene Cold Water Dispersible Products from *Blakeslea trispora*' of 4 December 2008 <sup>(1)</sup>. Similar products are produced also from synthetic lycopene, as mentioned in the Authority's opinion on safety of Synthetic Lycopene of 10 April 2008 <sup>(2)</sup>. As the Authority evaluated this specific use, it is necessary to authorise this use by the same residual levels that were considered during the evaluation.

- (7) It is necessary to take into account the specifications and analytical techniques for additives as set out in the Codex Alimentarius drafted by the Joint Expert Committee on Food Additives (JECFA). In particular, the specific purity criteria need to be adapted to reflect the limits for individual heavy metals of interest, where appropriate.
- (8) Directive 2008/128/EC should therefore be amended accordingly.
- (9) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health, and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS DIRECTIVE:

#### Article 1

The Annex I to Directive 2008/128/EC is amended in accordance with the Annex to this Directive.

#### Article 2

##### Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 September 2011 at the latest. They shall forthwith communicate to the Commission the text of those provisions. When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

#### Article 3

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

#### Article 4

This Directive is addressed to the Member States.

Done at Brussels, 17 January 2011.

For the Commission

The President

José Manuel BARROSO

<sup>(1)</sup> Scientific opinion of the panel on Dietetic Products, Nutrition and Allergies on a request from European Commission to carry out an additional assessment for 'Lycopene Cold Water Dispersible Products (CWD) from *Blakeslea Trispora*' as a food ingredient in the context of Regulation (EC) No 258/97. The EFSA Journal (2008) 893, 1-15.

<sup>(2)</sup> Scientific opinion of the panel on Dietetic Products, Nutrition and Allergies on a request from the European Commission on safety of synthetic lycopene. The EFSA Journal (2008) 676, 1-25.

## ANNEX

In Annex I to Directive 2008/128/EC the entry on E 160 d is replaced by the following:

## E 160 D LYCOPENE

(i) *synthetic lycopene***Synonyms**

Lycopene from chemical synthesis

**Definition**

Synthetic lycopene is a mixture of geometric isomeres of lycopenes and is produced by the Wittig condensation of synthetic intermediates commonly used in the production of other carotenoids used in food. Synthetic lycopene consists predominantly of all-trans-lycopene together with 5-cis-lycopene and minor quantities of other isomers. Commercial lycopene preparations intended for use in food are formulated as suspensions in edible oils or water-dispersible or water-soluble powder.

Colour Index No

75125

EINECS

207-949-1

Chemical name

$\Psi,\Psi$ -carotene, all-trans-lycopene, (all-E)-lycopene, (all-E)-2,6,10,14,19,23,27,31-octamethyl-2,6,8,10,12,14,16,18,20,22,24,26,30-dotriacontatridecaene

Chemical formula

 $C_{40}H_{56}$ 

Molecular weight

536,85

Assay

Not less than 96 % total lycopenes (not less than 70 % all-trans-lycopene)  
 $E_{1\text{ cm}}^{1\%}$  at 465 - 475 nm in hexane (for 100 % pure all-translycopene) is 3 450

**Description**

Red crystalline powder

**Identification**

Spectrophotometry

A solution in hexane shows an absorption maximum at approximately 470 nm

Test for carotenoids

The colour of the solution of the sample in acetone disappears after successive additions of a 5 % solution of sodium nitrite and 1N sulphuric acid

Solubility

Insoluble in water, freely soluble in chloroform

Properties of 1 % solution in chloroform

Is clear and has intensive red-orange colour

**Purity**

Loss on drying

Not more than 0,5 % (40 °C, 4 h at 20 mm Hg)

Apo-12'-lycopenal

Not more than 0,15 %

Triphenyl phosphine oxide

Not more than 0,01 %

Solvent residues

Methanol not more than 200 mg/kg,  
 Hexane, Propan-2-ol: Not more than 10 mg/kg each.  
 Dichloromethane: Not more than 10 mg/kg (in commercial preparations only)

Lead

Not more than 1 mg/kg

<b>(ii) from red tomatoes</b>	
<b>Synonyms</b>	Natural Yellow 27
<b>Definition</b>	Lycopene is obtained by solvent extraction of red tomatoes ( <i>Lycopersicon esculentum</i> L.) with subsequent removal of the solvent. Only the following solvent may be used: carbon dioxide, ethyl acetate, acetone, propan-2-ol, methanol, ethanol, hexane. The major colouring principle of tomatoes is lycopene, minor amounts of other carotenoid pigments may be present. Besides the colour pigments the product may contain oil, fats, waxes and flavour components naturally occurring in tomatoes.
Colour Index No	75125
EINECS	207-949-1
Chemical name	$\Psi,\Psi$ -carotene, all-trans-lycopene, (all-E)-lycopene, (all-E)-2,6,10,14,19,23,27,31-octamethyl-2,6,8,10,12,14,16,18,20,22,24,26,30-dotriacontatridecaene
Chemical formula	$C_{40}H_{56}$
Molecular weight	536,85
Assay	$E_{1\text{ cm}}^{1\%}$ at 465 - 475 nm in hexane (for 100 % pure all-translycopene) is 3 450. Content not less than 5 % total colouring matters
<b>Description</b>	Dark red viscous liquid
<b>Identification</b>	
Spectrophotometry	Maximum in hexane at ca 472 nm
<b>Purity</b>	
Solvent residues	Propane-2-ol Hexane Acetone Ethanol Methanol Ethylacetate Not more than 50 mg/kg, singly or in combination
Sulphated ash	Not more than 1 %
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
<b>(iii) from <i>Blakeslea trispora</i></b>	
<b>Synonyms</b>	Natural Yellow 27
<b>Definition</b>	Lycopene from <i>Blakeslea trispora</i> is extracted from the fungal biomass and purified by crystallisation and filtration. It consists predominantly of all-trans-lycopene. It also contains minor quantities of other carotenoids. Isopropanol and isobutyl acetate are the only solvents used in the manufacture. Commercial lycopene preparations intended for use in food are formulated as suspensions in edible oils or water-dispersible or water-soluble powder.

Colour Index No	75125
EINECS	207-949-1
Chemical name	$\Psi,\Psi$ -carotene, all-trans-lycopene, (all-E)-lycopene, (all-E)-2,6,10,14,19,23,27,31-octamethyl-2,6,8,10,12,14,16,18,20,22,24,26,30-dotriacontatridecaene
Chemical formula	$C_{40}H_{56}$
Molecular weight	536,85
Assay	Not less than 95 % total lycopenes and not less than 90 % all-trans-lycopene of all colouring matters $E_{1\text{ cm}}^{1\%}$ at 465 - 475 nm in hexane (for 100 % pure all-translycopene) is 3 450
<b>Description</b>	Red crystalline powder
<b>Identification</b>	
Spectrophotometry	A solution in hexane shows an absorption maximum at approximately 470 nm
Test of carotenoids	The colour of the solution of the sample in acetone disappears after successive additions of a 5 % solution of sodium nitrite and 1N sulphuric acid
Solubility	Insoluble in water, freely soluble in chloroform
Properties of 1 % solution in chloroform	Is clear and has intensive red-orange colour
<b>Purity</b>	
Loss on drying	Not more than 0,5 % (40 °C, 4 h at 20 mm Hg)
Other carotenoids	Not more than 5 %
Solvent residues	Propan-2-ol: Not more than 0,1 % Isobutyl acetate: Not more than 1,0 % Dichloromethane: Not more than 10 mg/kg (in commercial preparations only)
Sulphated ash	Not more than 0,3 %
Lead	Not more than 1 mg/kg'

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